

Application Number: 10/679,271

Reply To Office Action Of NOVEMBER 24, 2004

**Remarks**

Claims 1-26 were pending in this application. Applicant acknowledges Claim 27 has been withdrawn from consideration. Claims 1, 10, 24 and 25 have been amended. Claims 28-49 have been added. In the Office Action, the Examiner has rejected the claims 1-6, 8-12 and 15-22 under 35 U.S.C. §103(a) as unpatentable over U.S. Patent 4,176,153 to Weiler et al. (hereinafter "Weiler") in view of U.S. Patent 4,924,919 to Oyler (hereinafter Oyler). Claims 7, 13, 14, and 23-26 were rejected in view of the combination of Weiler and Oyler in further combination with other references which will be discussed further herein. The applicant notes that there are no 35 U.S.C. §102 rejections upon any of the claims 1-26.

Applicant has amended claim 1 to clarify how the container is held and clarify the location of the pressure application. As discussed below, new Claims 28-49 have been added. Although Claim 10 was not included in the 35 U.S.C. §112, second paragraph rejection, Applicants' have discovered a typographical error in Claim 10; subsequently, the dependency of Claim 10 has been corrected to depend from Claim 1 rather than Claim 10.

As an initial matter, it should be noted that the present invention is directed to a method of filling a container for a delivery device for introducing a fluidic substance to a patient. Such systems are desirable to control the volume and characteristics of the fluid in the container. Additionally, it is desirable to have a system that controls the fluidic levels and properties within the container. The container may have a flexible portion and a rigid portion. The method and device of the instant application includes a pressurization and sealing method which controls these parameters by applying a controlled pressure environment to: at least a portion of the exterior of the flexible component, the interior volume of the container, and the gas-liquid interface of the liquid. The pressure is within a pressure range that is greater than or equal to the vapor pressure of the fluid within the container. A controlled pressure is applied during sealing of the opening of the container. Optionally, the fluid meniscus formed within the interior volume of the container is manipulated by varying the pressure or by other means to increase or reduce the headspace to a predetermined range prior to the sealing and release of the container.

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***Claim Rejections under 35 USC § 112***

The Examiner has rejected Claim 24 and 25 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 24 and 25 have been amended to change their dependency from Claim 1 to claim 23, thereby providing antecedent basis for the term "hollow conical structure." In view of the foregoing amendments, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

***Claim Rejections under 35 USC 103***

In the Office Action, the Examiner has rejected claims 1-6, 8-12 and 15-22 under 35 U.S.C. §103(a) as unpatentable over U.S. Patent 4,176,153 to Weiler et al. (hereinafter "Weiler") in view of U.S. Patent 4,924,919 to Oyler (hereinafter Oyler).

Weiler teaches a method and device which is a variation of what is commonly known as "Form-Fill-Seal" or "Blow-Fill-Seal." Methods of standard Blow-Fill-Seal (BFS) manufacturing have been well established since the 1970s, as demonstrated by Weiler. However, various aspects of this process inherently limit the range of products that can be feasibly packaged in BFS containers. Most notably, heat sensitive products have issues with packaging in the BFS process due to the high operating temperatures encountered in the cycle. Furthermore, in a BFS process the container is formed and retained by the walls of a mold which produces a fixed volume container. Therefore, the retention features of Weiler serve as the mold for the production of the container of Weiler, which has a fixed volume. As is the case with BFS operations, Weiler requires the expansion of the container to contact the surface of the mold by application of a positive pressure within the container to form the fixed volume of the container. From the structure and description of Weiler, Weiler is unable to apply pressure to the interior of the container (and fluid) during the sealing operation since the filling head (and pressure applicator) is removed from the container prior to sealing. Although Weiler does disclose dispensing at a pressure within the container to expand the container, Weiler does not teach or suggest application of pressures on the exterior surface of the container, as the

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pressures on the outside surface of the container are limited by its contact with the mold, and for this aspect the Examiner has stated he must look to Oyler. Oyler teaches a method and device for filling a balloon with solid objects (articles) as a gift wrapping by reducing the pressure (with respect to ambient) on the exterior of the balloon. Oyler only describes placing a negative pressure on the exterior surface of the container and is silent as to the pressure parameters on the interior of the container, although it is presumed that the interior of Oyler is at ambient pressure. Therefore, Oyler is unable to modify the pressures on the interior of the container. From the drawings of Oyler, it would appear that Oyler produces a fixed volume container (as shown in Fig. 4, 5 and 6). Furthermore, the combination of Weiler and Oyler do not control the pressure on the interior and exterior of the container. The combination of Weiler and Oyler do not produce the claimed invention, as the pressures within the container, on the fluid, and on the external portion of the container in the resulting combination are not controllable during the sealing operation. A combination of the teachings of Weiler and Oyler produces a method/device which has different uncontrolled pressures on the interior and exterior of the container. The combination of Weiler and Oyler do not produce the claimed invention, as the resultant combination produces a container with a static volume which is not adaptable to the volume of the fluid dispensed, and produces a fixed volume container. Moreover, the combination of Weiler and Oyler does not teach or suggest using the vapor pressure of the liquid as a limiting factor. In fact, neither reference teaches any relation to vapor pressure. In contrast, the claimed invention subjects both the exterior and the interior volume of the container (including the fluid) to an environment having a predetermined pressure range which is greater than or equal to the vapor pressure of the fluid.

Furthermore, Weiler provides no motivation to modify the ambient pressures during delivery of the fluid to the container of Weiler. In fact, Weiler provides for venting of gas from the interior of the container to the exterior of the container, which by its very nature implies a difference in pressure. Adding the teachings of Oyler to Weiler does not change the nature of the pressure delivery to the interior of the container in the resulting combination other than to include applying a negative pressure to the exterior of the container which is necessarily different from the internal pressure of the container.

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Therefore, the combination of Weiler and Oyler do not produce the claimed invention, as the pressures within the container, on the fluid, and on the external portion of the container in the resulting combination are not the same. Additionally, none of the pressures in the resulting combination of Weiler and Oyler bear any relation to the vapor pressure of the fluid in the container. The Examiner should note, according to MPEP §2143.02, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to modify the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000). The claims as now amended have specific pressure applications which are not taught or suggested by Weiler, or Weiler in view of Oyler. The examiner may not appropriately rely on "the level of skill in the art" to provide the suggestion to make modifications to the Weiler device with the features of the Oyler to produce the instant invention.

Weiler also requires the internal pressure of the container to be at least initially greater than the pressure outside the container (which allows for the forming of the container). Oyler teaches reducing the pressure on the external surface of the container to form the container (a balloon). The pressures within Oyler are merely to expand the balloon of Oyler to a fixed volume (formed by the interior walls of the retainer of Oyler), and have no relation to the properties of the contents of the container. Neither Weiler nor Oyler alone or in combination teach or suggest the application of a single pressure equal to greater than vapor pressure of the fluid to an external portion of the container, the internal portion of the container, and the fluid within the container. Furthermore, the Examiner should note, according to MPEP §2143.02, that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Accordingly, the modification of Weiler with the pressures of Oyler would in effect change the principle of operation of the Weiler device/method to a vacuum forming type

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device, therefore would not render claim 1, as amended, *prima facie* obvious, since the primary principal of operation of Weiler would be changed.

Applicants also contend that Oyler is nonanalogous art, as it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Oyler is directed at a method and device for gift wrapping solid articles using a balloon. In contrast, Weiler, as well as, the applicant's invention relate to filling of fluidic medical devices. One skilled in the art of fluidic medical device filling would not be inclined to look to the field of gift wrapping to find the solutions to the problem being solved.

For all the reasons stated above, the combination of Weiler and Oyler do not produce the instant invention as claimed. Furthermore, the Applicants contend the record does not appear to establish the requisite motivation for combining Weiler and Oyler, as obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the case of the present application, the suggestion to combine the teachings of Weiler with the teachings of Oyler is not present.

Claim 7 is rejected under 35 U.S.C. §103(a) as unpatentable over Weiler in view of Oyler, in further view of U.S. Patent 3,382,642 to Shaw (hereinafter Shaw). The Applicant contends that claim 1 as now presently amended and dependent claim 7 distinguishes over Weiler in view of Oyler, in further view of Shaw and the rejection is respectfully traversed. In view of the amendments to Claim 1 and the differences between the cited references and the claimed invention discussed above, Applicants believe this rejection is now moot. Reconsideration and allowance of Claim 7 is respectfully requested.

Claims 13 and 14 are rejected under 35 U.S.C. §103(a) as unpatentable over Weiler in view of Oyler, in further view of U.S. Patent 5,170,609 to Bullock (hereinafter

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Bullock). The Applicant contends that claim 1 as now presently amended and dependent claims 13 and 14 distinguish over Weiler in view of Oyler, in further view of Bullock and the rejection is respectfully traversed. In view of the amendments to Claim 1 and the differences between the cited references and the claimed invention discussed above, Applicants believe this rejection is now moot. Reconsideration and allowance of Claims 13 and 14 is respectfully requested.

Claims 23-26 are rejected under 35 U.S.C. §103(a) as unpatentable over Weiler in view of Oyler, in further view of U.S. Patent 5,673,731 to Green (hereinafter Green). The Applicant contends that claim 1 as now presently amended and dependent claim 23-26 distinguishes over Weiler in view of Oyler, in further view of Green and the rejection is respectfully traversed. In view of the amendments to Claim 1 and the differences between the cited references and the claimed invention discussed above, Applicants believe this rejection is now moot. Reconsideration and allowance of Claims 23-26 is respectfully requested.

### New Claims

New claims 28-49 have been added to further define aspects of the invention, which are fully supported by the instant specification. Accordingly, no new matter has been added. New independent claim 28 has similar elements and structure as original Claim 1 but in addition recites the limitations of a rigid portion. For all of the reasons discussed previously, none of the references, alone or in combination, teach or suggest a method of filling and sealing containers with at least one rigid component and at least one flexible component in the steps outlined. Without discussing each in detail, it will be appreciated that the claims depending from Claim 28 recite additional features that are not taught or suggested by the prior art.

New independent claim 39 has similar elements and structure as original Claim 1 but in addition recites the limitations of a pressure range. For all of the reasons discussed previously, none of the references, alone or in combination, teach or suggest a method of filling and sealing containers within pressure range and at least one flexible component in the steps outlined. Without discussing each in detail, it will be appreciated that the claims

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depending from Claim 39 recite additional features that are not taught or suggested by the prior art.

### Conclusion

In view of the Remarks above, applicant respectfully submits that Claims 1-26 and 28-49 are in condition for allowance, and respectfully requests that the Examiner earnestly reconsider his rejections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Dated: March <sup>4</sup>, 2005.

Respectfully submitted,

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